DECLARATION UNDER 37 C.F.R. § 1.132 OF PATHIRAJA GUNATILLAKE

Sir:

I, Pathiraja Gunatillake, offer the following declarations as evidence in the prosecution of the patent application Serial No. 10/520,414, under the provisions of 37 C.F.R. § 1.132:

1. I received a PhD (Polymer Chemistry) from City University of New York, USA in 1983 and I am currently employed by the Commonwealth Scientific & Industrial Research Organization (CSIRO) as a Senior Principal Research Scientist.

2. THAT, I have worked in the field of polyurethane chemistry for 21 years.

3. THAT, I am the co-inventor on 9 issued US patents and co-author of 40 scholarly articles in the fields of polyurethane synthesis, structure property relationships, biostability/biocompatibility and biomedical applications and attached herewith is a copy of my *Curriculum Vitae*.

4. THAT, I am a co-inventor of the subject matter disclosed in the above-captioned application.

5. THAT, I have read and understand the rejections contained in the Office Action issued on February 3, 2009 in the above-captioned application.

6. THAT, I have read, I understand, and I am familiar with the technology disclosed in U.S. Patents 4,412,033 and 4,293,679.

7. THAT, I respectfully offer the following Remarks in rebuttal to the rejections raised in the present Office Action.

U.S. 4,412,033

8. THAT, U.S. 4,412,033 (hereinafter "LaBelle") discloses a one-part curable polyurethane prepolymer composition for use as an adhesive, coating or sealant.

9. THAT, the disclosed one-part curable polyurethane prepolymer composition comprises a liquid phase, i.e., "continuous phase," consisting of an isocyanate capped prepolymer and a solid phase consisting of a finely divided polyol (col. 3, ll. 55-65).

10. THAT, the disclosed one-part curable polyurethane prepolymer composition is "stable for at least 48 hours at ambient temperature" and "is curable at temperatures above 60 °C" (col. 3, ll. 39-44). By contrast, the compositions recited in Claim 11 begin curing when mixed at ambient temperature (for example 20°C) without the need of an external heat source.

11. THAT, the disclosed one-part curable polyurethane prepolymer composition undergoes "**no significant curing at temperatures below 60 °C, or even at temperatures as high as 85 °C**" (col. 9, ll. 16-18, emphasis added).

12. THAT, the disclosed compositions, because they consist of a two phase system (liquid/solid), requires the application of heat above 85 °C to initiate curing. This application of heat is necessary in order to dissolve the solid pentaerythritol particles (solid phase polyol) so these particles can begin to react with the liquid phase. Once sufficient heat is added to instigate curing, additional energy is then released in the form of the heat of reaction.

13. THAT, this energy derived from the heat of reaction, has clear consequences.

14. THAT, the Office Action makes the following assertion which does not take into consideration these consequences:

> A polyol, such as poly(caprolactone) triol, is end-capped with an isocyanate such as a diisocyanate, to form an isocyanate-

> terminated polyurethane prepolymer (see col. 6, line 46 to col. 9, line 3; claim 7) A curing agent, such as pentaerythritol, is added which links on polyurethane prepolymer to another (see col. 9, line 5 to col. 10, line 4). (Office Action dated February 3, 2009, beginning at the last sentence of page 3 and continuing to page 4, line 4.)

15. THAT, Exhibit 1, attached herewith, provides the calculations which support the following analysis of the reaction cited as an example by the Office Action. Isophorone diisocyanate is first reacted with poly(caprolactone) triol to form a prepolymer (liquid phase). Finely divided, solid pentaerythritol is then added. After heating the two phase system to the necessary temperature of 60 °C, curing begins according to LaBelle's disclosure. At this point there is an additional temperature rise due to the heat of reaction. As indicated in Exhibit 1, the adiabatic temperature rise can be calculated to be 43 °C. As such, the final temperature of the curing reaction will be 103 °C; and this is at the minimal temperature, not the "preferably above 85 °C" as disclosed by LaBelle at col. 3, ll. 42-43.

16. THAT, if the compositions disclosed by LaBelle were to be applied to human tissue, as are the compositions disclosed in the above-identified application, the compositions disclosed by LaBelle would not begin to cure. If curing was attempted, however, the minimal curing temperature of 60 °C would cause irreversible damage to tissue and this temperature taken together with the heat released due to the heat of reaction, has the potential to raise the skin temperature above *boiling water*! Accordingly, the compositions disclosed by LaBelle are not suitable for *in vivo* application.

17. THAT, in contrast, the compositions recited in the present claims are safe and biocompatible; they can be cured at ambient temperatures without external heating. The specification recites at page 21, ¶ 3:

> The curing crosslinking reaction can be carried out under mild temperature conditions. Typically, the reaction is preferably carried out at temperatures ranging from 20 to 30 °C. The catalyst

> concentration can be adjusted such the temperature of the reaction mixture does not exceed 60 °C, more preferably 40 °C.

18. THAT, the compositions recited in the present claims cure at temperatures significantly lower than those disclosed by LaBelle. This is because the polyol is not present as a solid, and, therefore, does not have to be melted to instigate curing.

19. THAT, the compositions disclosed by LaBelle are useful as adhesives, coatings, sealants, and the like. By contrast, the compositions recited in the present claims are useful for biomedical applications and, as such, must be biocompatible (see present claim 11). In addition, each of LaBelle's examples comprises a plasticizer, for example, HB-40. HB-40 is a high boiling hydrogenated aromatic compound that is only partially hydrogenated and, therefore, still contains both aromatic terphenyls and partially hydrogenated aromatic terphenyls. (Exhibit 2 is a copy of the MSD sheet for HB-40). Moreover, these necessary plasticizers, which comprise aromatic compounds which are considered cytotoxic, are unsuitable for bio-medical applications and, as such, render the compositions taught by LaBelle as non-biocompatible.

20. THAT, the present Office Action has rejected Claims 11-12 and 19-22 under 35 U.S.C. § 102(b), as allegedly anticipated by LaBelle. The Office Action states:

> In the instant case, the same product is made whether the diisocyanate is first added to the poly(caprolactone) triol and subsequently treated with pentaerythritol (as done by [LaBelle]) or if the diisocyanate is first added to pentaerythritol and subsequently treated with the poly(caprolactone) triol (as presently claimed).

21. THAT, the Office Action's assumption is incorrect as it relates to the importance of the order of addition disclosed by LaBelle. Specifically, if the reaction of a diisocyanate, poly(caprolactone) triol, and pentaerythritol were perfectly stoichiometric, then the products could be similar. Due to the multifunctional nature of the species involved, however, the distribution of different products formed varies depending on the order of addition.

22. THAT, if one conducts the sequence of reactions as disclosed by LaBelle, then when poly(caprolactone) triol is first reacted with a diisocyanate, the product mixture formed will comprise unreacted diisocyanate, a plurality of different species of isocyanate capped poly(caprolactone), *inter alia*, mono-, di- and tri-capped species, as well as a species that is the reaction product of two or more molecules of poly(caprolactone) triol linked by a diisocyanate. The distribution of these products will vary depending upon the polymerization conditions and the reactant ratios. Moreover, when pentaerythritol is subsequently added, it can react with any of the different poly(caprolactone)-comprising species present or with the unreacted isocyanate that is also present.

23. THAT, if one conducts the process recited in the present claims, wherein pentaerythritol is first reacted with a diisocyanate, different species of isocyanate capped pentaerythritol, including mono-, di-, tri- and tetra-capped species, as well as multiple molecules of pentaerythritol linked by diisocyanates will be formed. When the first step of the process recited in the claims is allowed to reach completion, the result will be mainly linked pentaerythritol molecules capped with diisocyanate and unreacted diisocyanate. When poly(caprolactone) triol is subsequently added, it can then react with the linked pentaerythritol species present or with the unreacted isocyanate.

24. THAT, the complexity of possible reactions that can occur under the conditions disclosed by LaBelle results in a composition not recited in the present claims. The artisan of ordinary skill will understand the complex chemistry involved in LaBelle's order of addition, and, therefore, the critical role that the order of addition plays in reactions of this type. Attached herewith is Exhibit 5 which is a GPC trace showing the products formed from the reaction of pentaerythritol with 1,6-hexamethylene-diisocyanate (1:6 molar ratio). This chromatograph indicates that the products formed by the reaction disclosed by LaBelle represent a complex mixture. This GPC plot shows a number of peaks each of which is assigned to a particular reaction product, reaction intermediate, or starting material as listed in Exhibit 3. As such, the compositions formed by LaBelle's crosslinking with excess water does not yield a

product having low polydispersity.

25. THAT, the compositions disclosed by LaBelle comprise (a) generally a continuous (liquid) phase of isocyanate capped prepolymer and (b) a solid phase comprising a polyol, for example, pentaerythritol. This heterogeneity of LaBelle's system, i.e., a solid phase within a continuous phase, provides a further reaction product complexity due to the unpredictable reaction kinetics that will now take place between isocyanate and hydroxyl groups. The concentration of pentaerythritol will vary within the matrix of the composition as the solid particles undergo melting. Therefore, as a result of LaBelle's solid/continuous phase system, products will be formed that are outside the scope of those compositions formed by the order of addition as recited in the present claims.

26. THAT, as a result the chemical species that make up LaBelle's cured products will differ in their corresponding microstructures because LaBelle's compositions will comprise varying amounts chemical species not formed by the recited process. This directly translates to measurable differences in the physical properties of the cured products of Labelle versus the compositions formed by the process recited in the claims. The system of LaBelle will be less well crosslinked in comparison to the compositions of the present invention due to inadequate mixing of NCO and OH (as a consequence of the presence of a particulate polyol). Hence, this would be reflected in inferior mechanical strength and greater water absorption due to the presence of free OH functions.

U.S. 4,293,679

27. THAT, U.S. 4,293,679 (hereinafter "Cogliano"), discloses crosslinked polyurethane particles prepared from a composition comprising, a water reactant and a prepolymer comprising at least one isocyanate capped polyol.

28. THAT, the present Office Action has rejected Claims 11-12 and 19-22 under 35 U.S.C. § 102(b), as allegedly anticipated by Cogliano. The Office Action states:

> Based on the substantially identical process using identical components, the Examiner has a reasonable basis to believe that the properties claimed in the present invention [i.e., a compressive strength in the range of 0.05-80 MPa and a pore size in the range of 150-300 microns] are inherent in the composition of [Cogliano].

29. THAT, the Office Action's assumption is incorrect as it relates to the disclosure of Cogliano.

30. THAT, specifically, Cogliano discloses the reaction of a polyoxyethylene glycol (PEG) with a molar excess of diisocyanate to form an isocyanate capped polyurethane product (A) (column 5, lines 7-12). Separately, a polyol, i.e., pentaerythritol, is reacted with a large molar excess of diisocyanate to form an isocyanate capped polyurethane intermediate product (B). These two products are then blended and subsequently crosslinked (column 5, lines 16-26). The crosslinking is affected by a large excess of water. Curing the composition in the presence of water results in a polymer that is largely amine terminated rather than urethane linked. Much of the isocyanate will undergo reaction with water to form amine groups. A summary of this reaction sequence is depicted in Exhibit 4.

31. THAT, in contrast, the present claims recite two prepolymers reacting with each other. In the reaction recited in the present claims, the hydroxyl group functions as the only proton donor source, whereas Cogliano utilizes water as the only proton donor source. The reaction recited in the present claims, therefore, largely results in the formation of urethane linkages. Furthermore, the reaction recited in the present claims will result in compositions that are amine free.

32. THAT, the present claims recite that the reaction product of a low molecular weight multifunctional core molecules and an isocyanate which is subsequently reacted with a linear, star, dendrimer or soft segment forming hyperbranched functional oligomer having degradable arms. Therefore, the present claims recite reacting a first component with an isocyanate prior to the addition of a second component. By contrast, Cogliano discloses that both components are reacted with excess isocyanate prior to combining

the two for crosslinking. As such, the artisan would recognize that combining two components having no available hydroxyl groups, as disclosed in Cogliano, versus an order of addition wherein one component has free hydroxyl groups would yield vastly different compositions.

33. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements, perjury, and the like so made are punishable by fine or imprisonments, or both, under Section 1001 of Title 18 of the United States Code and that any such willful false statement or perjury may jeopardize the validity of the application or any patent issued thereon.

Pathiraja Gunatillake

July 31, 2009
Date

EXHIBIT 1

Calculation of the adiabatic temperature rise resulting from the heat of reaction generated in the systems of "LaBelle" and of the present disclosure.

Pentaerythritol (PE), polycaprolactone triol (PCL900) and isophorone diisocyanate (IPDI) are reacted together in the amounts listed in Table I under the conditions of the present disclosure and under the conditions disclosed by LaBelle.

TABLE I

	Mn	Functionality	g/mol Funct Grps	For 100g	Moles Funct Grps
IPDI	222.3	2	111.15	39.96	0.3594
PCL900	900.0	3	300.0	53.92	0.1797
PE	136.15	4	34.04	6.12	0.1797

Present Disclosure: IPDI and PE are reacted together to form a liquid prepolymer at ambient temperature. This prepolymer is then reacted with PCL900 starting at 20°C (ambient temperature). The expected exotherm[1] is:

0.1797 mol urethane x 24000 cal/mol (H_f)/100 g polymer = 43.14 °C

wherein H_f is the enthalpy of formation for a urethane linkage. For the disclosed process the exotherm is approximately 43°C that when taken together with the starting temperature results in a reaction temperature of approximately 63 °C.

LaBelle Disclosure: IPDI and PCL900 are reacted together to form a liquid prepolymer at room temperature. PE is then mixed into the prepolymer as a solid, and the temperature raised to at least 60°C to initiate the reaction, because as LaBelle discloses "no reaction occurs below 60 °C." The expected exotherm is 43°C, the same as above since there are same number of moles of urethane formed, hence the overall temperature of the reaction is 60 °C + 43 °C = 103 °C.

Also note that the temperature has been calculated for the minimum starting temperature (i.e., 60 °C), rather than the preferred initiation temperature of 85°C of LaBelle in which case the temperature would reach 85 °C + 43 °C = 128 °C.

1. Exotherm heat of 24,000 cal/mol urethane taken from S.-T.Lee and N.S.Ramesh, Polymeric Foams: Mechanisms and Materials, CRC Press, Boca Raton, FL, 2004, (page 177).

Solutia Inc.

Material Safety Data Sheet

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: HB-40® Plasticizer

Reference Number: 000000000368 Date: 01/11/2008

Company Information:

United States:
Solutia Inc.
575 Maryville Center Drive, P.O. Box 66760
St. Louis, MO 63166-6760
Emergency telephone: Chemtrec: 1-800-424-9300
International Emergency telephone: Chemtrec: 703-527-3887
Non-Emergency telephone: 1-314-674-6661

Canada:
Solutia Canada Inc.
6800 St. Patrick Street
LaSalle, PQ H8N 2H3
Emergency telephone: CANUTEC: 1-613-996-6666
Non-Emergency telephone: 1-314-674-6661

Mexico:
Solutia MEXICO, S. DE R.L. DE C.V.
Prol. Paseo de la Reforma 2654
Local 501, Piso-5
Col. Lomas Altas
11950 Mexico, D.F.
Emergency telephone: SETIQ: (in Mexico) 01-800-002-1400
Non-Emergency telephone: (in Mexico) 01-55-5259-6800

Brazil:
Solutia Brazil Ltd.
Avenue Carlos Marcondes, 1200
CEP: 12241-420-São José dos Campos/SP-Brazil
Emergency telephone: 55 12 3932 7100 (PABX)
Non-Emergency telephone: 55 11 3146 1800 (PABX)

2. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Form:	oily, liquid
Colour:	clear to pale yellow
Odour:	characteristic

WARNING STATEMENTS

CAUTION!
May cause eye irritation
May cause skin irritation
May cause respiratory tract irritation

POTENTIAL HEALTH EFFECTS

Likely routes of exposure:	eye and skin contact inhalation
Eye contact:	Moderately irritating to eyes.
Skin contact:	Moderately irritating to skin. No more than slightly toxic if absorbed. Repeated contact may cause a drying, solvent like action on the skin.
Inhalation:	Moderately irritating if inhaled. No more than slightly toxic if inhaled. Elevated processing temperatures may cause release of vapours which are irritating if inhaled. Significant adverse health effects are not expected to develop under normal conditions of exposure.
Ingestion:	No more than slightly toxic if swallowed. Significant adverse health effects are not expected to develop if only small amounts (less than a mouthful) are swallowed.
Signs and symptoms of overexposure:	headache dizziness/incoordination nausea/vomiting loss of consciousness vertigo confusion anxiety laboured breathing drowsiness

Refer to Section 11 for toxicological information.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS No.	Average concentration	Concentration range	Units
terphenyl, hydrogenated	61788-32-7		>74.0 - <87.0	%
quaterphenyls and higher polyphenyls, partially hydrogenated	68956-74-1		<=18.0	%
terphenyl	26140-60-3		>3.0 - <8.0	%

4. FIRST AID MEASURES

If in eyes:	Immediately flush with plenty of water. If easy to do, remove any contact lenses. Get medical attention if irritation persists. Remove material from skin and clothing.
If on skin:	Immediately flush the area with plenty of water. Remove contaminated clothing. Wash skin gently with soap as soon as it is available. Get medical attention if irritation persists. Wash clothing before reuse.

If inhaled:	Remove patient to fresh air. If not breathing, give artificial respiration. If breathing is difficult give oxygen. Remove material from eyes, skin and clothing.
If swallowed:	Immediate first aid is not likely to be required. A physician or Poison Control Center can be contacted for advice. Wash heavily contaminated clothing before reuse.

5. FIRE FIGHTING MEASURES

Fire point: 212 C	Cleveland Open Cup
Hazardous products of combustion:	carbon dioxide; carbon monoxide (CO); soot; smoke; hydrocarbons
Extinguishing media:	Water spray, foam, dry chemical, or carbon dioxide
Unusual fire and explosion hazards:	None known
Fire fighting equipment:	Firefighters, and others exposed, wear self-contained breathing apparatus. Equipment should be thoroughly decontaminated after use.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions:	Use personal protection recommended in section 8.
Environmental precautions:	Keep out of drains and water courses.
Methods for cleaning up:	Contain large spills with dikes and transfer the material to appropriate containers for reclamation or disposal. Absorb remaining material or small spills with an inert material and then place in a chemical waste container. Flush spill area with water.

Refer to Section 13 for disposal information and Sections 14 and 15 for reportable quantity information.

7. HANDLING AND STORAGE

Handling
Avoid contact with eyes, skin and clothing.
Avoid breathing vapour or mist.
Keep container closed.
Use with adequate ventilation.
Wash thoroughly after handling.

Emptied containers retain vapour and product residue. Observe all recommended safety precautions until container is cleaned, reconditioned or destroyed. Do not cut or weld on or near this container, even when empty. Container retains vapour and product residue. The reuse of this material's container for non industrial purposes is prohibited and any reuse must be in consideration of the data provided in this material safety data sheet.

Storage
General: Stable under normal conditions of handling and storage.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Airborne exposure limits:	(ml/m3 = ppm)
HB-40®	No specific occupational exposure limit has been established.
terphenyl, hydrogenated	ACGIH TLV: 0.5 ml/m3 ; 4.9 mg/m3 ; ; 8-hr TWA Mexican OEL: 0.5 ml/m3 ; 5 mg/m3 ; ; 8-hr TWA OSHA PEL: 0.5 ml/m3 ; 5 mg/m3 ; ; 8-hr TWA
terphenyl	ACGIH TLV: 5 mg/m3 ; ; ceiling OSHA PEL: 1 ml/m3 ; 9 mg/m3 ; ; ceiling Mexican OEL: 0.5 ml/m3 ; ; ceiling
Eye protection:	Wear chemical goggles. Have eye flushing equipment available.
Hand protection:	Wear chemical resistant gloves. Consult the glove/clothing manufacturer to determine the appropriate type glove/clothing for a given application.
Body protection:	Wear suitable protective clothing. Consult the glove/clothing manufacturer to determine the appropriate type glove/clothing for a given application. Wear full protective clothing if exposed to splashes. Wash contaminated skin promptly. Launder contaminated clothing and clean protective equipment before reuse. Wash thoroughly after handling.
Respiratory protection:	Avoid breathing vapour or mist. Use approved respiratory protection equipment (full facepiece recommended) when airborne exposure limits are exceeded. If used, full facepiece replaces the need for face shield and/or chemical goggles. Consult the respirator manufacturer to determine the appropriate type of equipment for a given application. Observe respirator use limitations specified by the manufacturer.
Ventilation:	Provide natural or mechanical ventilation to control exposure levels below airborne exposure limits. If practical, use local mechanical exhaust ventilation at sources of air contamination such as processing equipment.

Components referred to herein may be regulated by specific Canadian provincial legislation. Please refer to exposure limits legislated for the province in which the substance will be used.

9. PHYSICAL AND CHEMICAL PROPERTIES

Flash point:	184 C 170 C	Cleveland Open Cup Pensky-Martens closed tester
Autoignition temperature:	373 C	ASTM E-659
Specific gravity:	1.001 - 1.009 @ 25 C	

Boiling point :	359 C @ 1,013 hPa
Water solubility:	0.061 mg/l @ 20 C

NOTE: These physical data are typical values based on material tested but may vary from sample to sample. Typical values should not be construed as a guaranteed analysis of any specific lot or as specifications for the product.

10. STABILITY AND REACTIVITY

Conditions to avoid:	All sources of ignition.
Materials to avoid:	Contact with strong oxidizing agents.
Hazardous reactions:	Hazardous polymerization does not occur.
Hazardous decomposition products:	None known;

11. TOXICOLOGICAL INFORMATION

Results from Solutia sponsored studies or from the available public literature are described below.

Acute animal toxicity data

Oral:	LD50 , rat, > 10,000 mg/kg , Practically nontoxic following oral administration.
Dermal:	LD50 , rabbit, > 2,000 mg/kg , No more than slightly toxic
Inhalation:	LC50 , rat, > 4.7 mg/l , ,
Eye irritation:	rabbit , Practically non irritating to eyes (rabbit)., 24 h
Skin irritation:	rabbit , Practically non irritating to skin (rabbit)., 24 h
Skin sensitization:	Human experience , Predictive patch testing on human volunteers did not produce irritation or sensitization. Data obtained on similar product.
Repeat dose toxicity:	rabbit, 2,000 mg/kg, dermal, , , Repeated skin exposure produced irritation in animal studies.
Repeat dose toxicity:	mouse, , inhalation, repeat dose, , Minor effects (less than lesions) were present in some animals at the end of the observation period. Data obtained on similar product.
Repeat dose toxicity:	rat, , inhalation, 13 weeks, , Produced effects on body weight, serum enzymes and/or organ weights in repeat dose studies.
Repeat dose toxicity:	mouse, , inhalation, 28 days, , No adverse treatment related effects. Data obtained on similar product.

Repeat dose toxicity:	monkey & rat & hamster, , inhalation, 26 weeks, , Produced effects on body weight, serum enzymes and/or organ weights in repeat dose studies. Data obtained on similar product.
Repeat dose toxicity:	rat, 15 mg/kg, diet, 13 weeks, , Produced effects on body weight, serum enzymes and/or organ weights in repeat dose studies.
Repeat dose toxicity:	mouse, 250 mg/kg, gavage, subchronic, , Repeated oral administration caused kidney and liver effects. Data obtained on similar product.
Developmental toxicity:	rat, gavage, , Effects on offspring only observed with maternal toxicity.
Carcinogenicity:	mouse, dermal, chronic, No treatment-related effects were observed. Data obtained on similar product.
Mutagenicity:	No genetic effects were observed in standard tests using bacterial and animal cells. No genetic effects were observed in standard tests using whole animals.

Components

Data from Solutia studies and/or the available scientific literature on the components of this material which have been identified as hazardous chemicals under the criteria of the OSHA Hazard Communication Standard (29 CFR 1910.1200) or the Canadian Hazardous Products Act are discussed below if present.

terphenyl, hydrogenated	Practically nontoxic following oral administration. Practically nontoxic after skin application in animal studies. Practically non irritating to eyes (rabbit). Practically non irritating to skin (rabbit). Produced effects on body weight, serum enzymes and/or organ weights in repeat dose studies. No genetic effects were observed in standard tests using bacterial and animal cells.
terphenyl	Practically nontoxic to slightly toxic following oral administration. Moderately toxic based on animal inhalation exposure studies. Produced effects on body weight, serum enzymes and/or organ weights in repeat dose studies. Produced no dermal sensitization (guinea pigs).

12. ECOLOGICAL INFORMATION

Environmental Toxicity

Invertebrates	48 h, EC50 Water flea (Daphnia magna) 1.3 mg/l EC50/LC50 greater than water solubility.
Fish:	96 h, LC50 Rainbow trout (Oncorhynchus mykiss) > 1000 mg/l EC50/LC50 greater than water solubility. 96 h, LC50 Bluegill sunfish (Lepomis macrochirus) > 100 mg/l EC50/LC50 greater than water solubility. 96 h, LC50 Fathead minnow (Pimephales promelas) > 1000 mg/l EC50/LC50 greater than water solubility.

Algae:	96 h, LC50 Algae 44 mg/l EC50/LC50 greater than water solubility. 96 h, LC50 Algae 56 mg/l EC50/LC50 greater than water solubility.

Environmental fate

Biodegradation

Inherently biodegradable.

13. DISPOSAL CONSIDERATIONS

US EPA RCRA Status:	This material when discarded may be a hazardous waste as that term is defined by the Resource Conservation and Recovery Act (RCRA), 40 CFR 261.24, due to its toxicity characteristic. This material should be analyzed in accordance with Method 1311 for the compound(s) below.
US EPA RCRA hazardous waste number:	D018 Compound/Characteristic: BENZENE
Disposal considerations:	Consult 40 CFR 268.40 or appropriate local regulations for concentration based standards.
Miscellaneous advice:	Local, state, provincial, and national disposal regulations may be more or less stringent. Consult your attorney or appropriate regulatory officials for information on such disposal. This product should not be dumped, spilled, rinsed or washed into sewers or public waterways.

14. TRANSPORT INFORMATION

The data provided in this section is for information only. Please apply the appropriate regulations to properly classify your shipment for transportation.

US DOT
Other: Not regulated for transport.

Canadian TDG
Other: Not regulated for transport.

ICAO/IATA Class
Other: This material is not regulated under IATA or ICAO for air transportation.

15. REGULATORY INFORMATION

All components are in compliance with the following inventories: U.S. TSCA, Canadian DSL, EU EINECS, Australian AICS, Phillipine PICCS, Korean, New Zealand, Chinese

Canadian WHMIS classification: Not Controlled

SARA Hazard Notification:

Hazard Categories Under Title III Rules (40 CFR 370):	Not applicable
Section 302 Extremely Hazardous Substances:	Not applicable
Section 313 Toxic Chemical(s):	Not applicable

CERCLA Reportable Quantity:

Not applicable

This product has been classified in accordance with the hazard criteria of the Canadian Controlled Products Regulation and the MSDS contains all the information required by the Canadian Controlled Products Regulation.

Refer to Section 11 for OSHA/HPA Hazardous Chemical(s) and Section 13 for RCRA classification.

Safety data sheet also created in accordance with Brazilian law NBR 14725

16. OTHER INFORMATION

Product use: Plasticizer

Reason for revision: Routine review and update

	Health	Fire	Reactivity	Additional Information
Suggested NFPA Rating	1	1	0	
Suggested HMIS Rating:	1	1	0	C

Prepared by the Solutia Hazard Communication Group. Please consult Solutia @ 314-674-6661 if further information is needed.

EXHIBIT 3

Description of GPC trace Exhibit 5

The GPC trace of Exhibit 5 illustrates the reaction products of pentaerythritol (PE) with 1,6-hexamethylenediisocyanate (HDI), (1:6 molar ratio). The numbers on the chromatogram are with respect to polystyrene standards. The peaks at 152 and 437 are baseline noise due to solvent and are present in a blank reference.

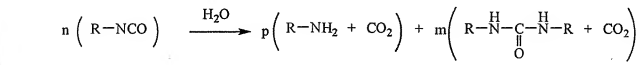
The following are identifiable products:

1. Peak at 216 is unreacted HDI.
2. Peak at 1128 is PE functionalized with 4 HDI.
3. Peak at 2038 is two PE's linked and functionalized fully with 7 HDI.
4. Peak at 2926 is 3 PE's functionalized with 10 HDI.
5. Peak at 3797 is 4 PE's functionalized with 13 HDI.

Note that there is a very broad distribution that is typical of this type of reaction. Also the molecular weight at the upper end corresponds to more than 30 PE linked together.

EXHIBIT 4

The reaction scheme below illustrates the crosslinking with excess water as disclosed by Cogliano:

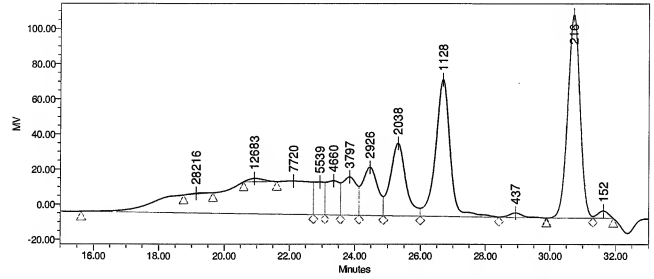


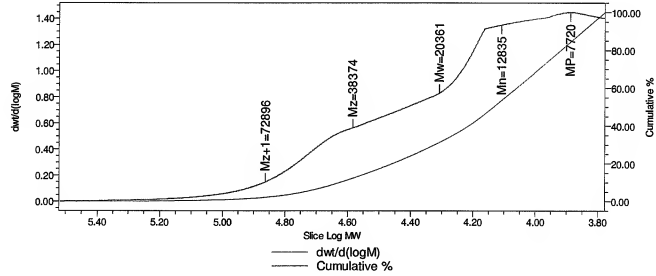
wherein n is the number of moles of isocyanate, R represents the remainder of the prepolymer, p + 2m = n, and p > m. The significant difference between the process disclosed by Cogliano and the present disclosure is that m will be much less than the value of p because of the large excess of water present. In the present disclosure, however, p is either 0 (or very close to it), and hence m >> p. In the process disclosed by Cogliano, a significant amount of urethane, as represented by the value of m is always present and, as such, the reverse is true in Cogliano; p > m.

The effect of Cogliano's stoichiometry is that his compositions comprise a large amount of amine terminated oligomers (i.e., the value of p is high), whereas the present disclosure recites compositions having a high degree of crosslinking (i.e., m >> p).

PN008-02-55 GPC Individual Report

Sample Set:	090508 THF	GPC System:	PolyNovo2 THF
Acquired By:	Daniel	Processing Method:	THF
Date Acquired:	8/05/2009	Instrument Method:	THF
Curve Used:	1747	Project Name:	THF





	Sample Name	Result ID	Sign Off Full Name	Sign Off Date	Sign Off Reason
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Appendix A

CURRICULUM VITAE

Pathiraja (Thilak) Gunatillake
CSIRO Molecular & Health & Technologies, Bag 10 Clayton South MDC, Clayton 3169.
Ph: 61 3 9545 2501; E-mail: Thilak.Gunatillake@csiro.au

CITIZENSHIP: Australian
DATE OF BIRTH: 28 January 1949
PLACE OF BIRTH: Colombo, Sri Lanka

POSITIONS HELD:

- **Nov 08 –present: Senior Principal Research Scientist: CSIRO Molecular & Health Technologies**
- **2004-Nov 08: Chief Scientific Officer, PolyNovo Biomaterials**
- 2000-2004: Senior Principal Research Scientist, Project Leader, Biomaterials, CSIRO Molecular Science
- 1993-1999: Principal Research Scientist, CSIRO Molecular Science
- 1988-1993: Senior Research Scientist, CSIRO Division of Chemicals and Polymers
- 1984-1988: Research Associate/ Adjunct Assistant Professor, Research Foundation of City University New York and College of Staten Island, USA
- 1978-1983: Teaching Assistant, College of Staten Island New York USA
- 1972-1977: Research Officer, Ceylon Institute of Scientific and Industrial Research, Sri Lanka
- 1972: Assistant Lecturer, University of Ceylon, Sri Lanka

UNIVERSITY EDUCATION:

- 1983 - Doctor of Philosophy in Polymer Chemistry, City University of New York, USA
- 1982 - Master of Philosophy, Polymer Chemistry, City University of New York, USA
- 1971 - Bachelor of Science (Hons), University of Ceylon, Sri Lanka

AWARDS/SCHOLARSHIPS:

- 2008: Elected 'Fellow Biomaterials Science and Engineering" (FBSE) by the International Union of Societies for Biomaterials Science & Engineering
- 2005: CSIRO Medal (Research Excellence)
- 2002: Sir Ian McLennan Achievement for Industry Award
- 2001 CSIRO Medal (Business Excellence)
- Inaugural Business Excellence Award 2000 (Technology Transfer)
- Fulbright Travel Award, 1977
- University Exhibition Award, 1968
- Science Scholarship (Sri Lanka), 1962-1971

PROFESSIONAL ACTIVITIES:

- Royal Australian Chemical Institute (Member)
- Australasian Society for Biomaterials & Tissue Engineering (Vice President 09)
- Wound Management Association of Victoria (Member)

PATENTS

1. Crompton C, **Gunatillake PA**, Griffiths I, Moore TG, Adhikari A, Greenwood J. 2008. Biocompatible Liquid Bandage & Tissue Sealant Compositions-EASE: Australian Provisional Patent Application 2008902760.

2. **Gunatillake PA**, Mayadunne R, Adhikari R et al Delivery Device: Australian Provisional Patent Applications 2008903974

3. Moore TG, **Gunatillake PA**, Adhikari R. 2007. High Modulus Polyurethanes and Polyurethaneureas. Australian Provisional Patent Application 2007905409; PCT/AU2008/001460.

4. **Gunatillake PA**, Mayadunne R, Adhikari R, Ramshaw JAM, Werkmeister J. et al. 2007. Biocompatible Biodegradable Polymer Formulations. International Patent Application PCT/AU2007/001085.

5. **Gunatillake PA**, Moore T, Adhikari R. 2006. Biodegradable Polyurethane Polyurethaneurea Compositions (Chain extenders). International Patent Application PCT/AU2006/001380.

6. **Gunatillake PA**, Adhikari R, Moore TG. 2005. Biodegradable Polyurethane and Polyurethane Ureas. PCT/AU2005/000436; WO2005089778-A1; US2006051394-A1; EP1729783-A1; AU2005223917-A1.

7. **Gunatillake PA**, Adhikari R, Griffiths I, Padsalgikar A. 2005. Polyurethanes. WO2005052019-A1; EP1701988-A1; US2007027285-A1.

8. **Gunatillake PA**, Mayadunne R, Adhikari R. 2005. Biocompatible Polymer Compositions for Dual or Multi Staged Curing: PCT/AU2005/000305; WO2005085312-A1; US2005197422-A1; EP1720925-A1; AU2005219452-A1.

9. **Gunatillake PA**, Mayadunne R, Adhikari R. 2004. Polymer Compositions for Dual or Multi Staged Curing: PCT20050303; WO2005085313-A1; EP1720926-A1; AU2005219453-A1; US2007225387-A1.

10. **Gunatillake PA**, McCarthy SJ, Meijs GF, Adhikari R. 2003. Siloxane-Containing Polyurethane-Urea Compositions. WO200064971-A; EP1192214-A; US2002028901-A1; AU200039472-A

11. J Watling, JL Jeffery, **PA Gunatillake**, TC Hughes. Improved Biomedical Compositions: Australian Provisional Patent Application # 2002950469 (PCT filed, July 2003)

12. **Gunatillake PA**, Adhikari R. 2002. Biodegradable polyurethane/urea compositions. PCT Application no PCT/AU03/00935; WO2004009227-A2; AU2003281481-A1; EP1572339-A2; TW200403268-A; US2005238683-A1; JP2006510747-W; CN1774460-A.

13. **Gunatillake PA**, McCarthy SJ, Meijs GF, Adhikari R. 2001. Shape Memory Polyurethane or Polyurethane-urea Polymers. WO200107499-A; US 2002161114-A1; EP1203038-A; AU200057974-A

14. **Gunatillake PA**, McCarthy SJ, Meijs GF, Adhikari R.1999. Non-Elastomeric Polyurethane Compositions. WO9950327-A; EP1078010-A; US6437073-B1; AU740402-B

15. **Gunatillake PA**, Meijs GF, Adhikari R. 1998. Silicon-Containing Chain Extenders. WO9903863; EP1000070-B1; US6420452-B1; AU9882013-A

16. **Gunatillake PA**, McCarthy SJ, Meijs GF. 1998. Process for Purification of Polyethers. International Patent Application PCT/AU98/00497; WO9901496A

17. **Gunatillake PA**, Meijs GF. 1998. Silicon-Based Polycarbonates. WO9854242-A; EP984997-B1; US7026423-B2; Au734927-B.

18. **Gunatillake PA**, Meijs GF, McCarthy SJ. 1996. Polysiloxane-containing polyurethane elastomeric compositions. WO9813405-A; EP938512-B1; EP1254916-A2; US6627724-B2

19. **Gunatillake PA**, Meijs GF, Rizzardo E. 1991. Poly(alkylene oxides). WO9209647-A1; AU642799-B; US5,403,912-A; EP559739-B1

20. Meijs GF, Rizzardo E, **Gunatillake PA**, Brandwood A, Schindhelm K. 1991. Polyurethane or Polyurethane-Urea Elastomeric Compositions. WO9200338-A; EP536223-B1; US5393858-A; AU657267-B

PUBLICATIONS

*[**Note: From 2004 to 2008, Dr Gunatillake was on secondment to PolyNovo Biomaterials and a major part of the research & development work conducted over that period remains as unpublished company confidential information**]*

1. Adhikari R, **Gunatillake PA**, Griffiths I, et al. Biodegradable injectable polyurethanes: Synthesis and evaluation for orthopaedic applications. *Biomaterials* Volume: 29(28): 3762-3770, 2008. [Impact=6.262 ; Citations 0]

2. Field JR, **Gunatillake P**, Adhikari R, et al. Use of biodegradable urethane-based adhesives to appose meniscal defect edges in an ovine model: a preliminary study. *Aust. Vet. J.* 86(6): 229-234, 2008. [Impact=0.595 ; Citations 0]

3. Dearman B, Rofe A, **Gunatillake PA**, et al. In vivo wound study assessing the safety and efficacy of a novel biodegradable polymer scaffold in preventing contraction, and integrating to form a neo-dermis. *Wound Rep. Regen.* 15(6): A113-A113, 2007. [Impact= ; Citations 0]

4. Li A, **Gunatillake T**, Crompton K, et al. Novel biodegradable polyurethanes as a scaffold for skin substitutes - An in vitro evaluation. *Wound Rep. Regen.* 15(6): A114-A114, 2007. [Impact= ; Citations 0]

5. Tatai L, Moore TG, Adhikari R, **Gunatillake PA** et al. Thermoplastic biodegradable polyurethanes: The effect of chain extender structure on properties and in-vitro degradation. *Biomaterials* Volume: 28(36): 5407-5417, 2008. [Impact=6.262 ; Citations = 3]

6. Bonzani IC, Adhikari R, Houshyar S, **Gunatillake PA** et al. Synthesis of two-component injectable polyurethanes for bone tissue engineering. *Biomaterials* Volume: 28(3): 423-433, 2007. [Impact=6.262 ; Citations =14]

7. **Gunatillake, P.A.**, Mayadunne, R., Adhikari, R. (2006). Recent Developments in Synthetic Biodegradable Polymers. *Biotechnology Annual Review*, 12:301-347. [Impact = ; Citations =4]

8. Moore T, Adhikari R, **Gunatillake PA**. Chemosynthesis of bioresorbable poly(gamma-butyrolactone) by ring-opening polymerisation: a review. *Biomaterials*. 26(18): 3771-3782, 2007. [Impact=6.262 ; Citations =5]

9. Simmons A, Hyvarinen J, Odell RA, **Gunatillake PA** et al. Long-term in vivo biostability of poly(dimethylsiloxane)/poly(hexamethylene oxide) mixed macrodiol-based polyurethane elastomers
Source. *Biomaterials*, 25(20): 4887-4900, 2004. [Impact=6.262 ; Citations =18]

10. Biodegradable Synthetic Polymers for Tissue Engineering: **PA Gunatillake** and R Adhikari. European Cells & Materials 2003, 5, 1-16. [Impact=; Citations =55]

11. Effect of Polydimethylsiloxane Macrodiol Molecular Weight on Properties of Siloxane: R. Adhikari, **PA Gunatillake** and M. Bown. J. Appl. Polym. Sci. 2003, 90, 6, 1565-1573 [Impact=; Citations =6]

12. Designing Biostable Polyurethane Elastomers for Biomedical Applications: **PA Gunatillake**, DJ Martin, GF Meijs, SJ McCarthy and R Adhikari: Aust. J. Chem, 2003, 56, 545-557. [Impact=2.36; Citations =16]

13. Low-modulus siloxane-polyurethanes. Part II. Effect of chain extender structure on properties and morphology. Author(s): Adhikari R, **Gunatillake PA**, McCarthy SJ, et al. *J Appl. Polym. Sci.* 87(7): 1092-1100, 2003. [Impact=1.008 ; Citations =2]

14. Low Modulus Siloxane-Based Polyurethanes: Effect of 1,3-Bis(4-hydroxybutyl)1,1,3,3,-tetramethyldisiloxane (BHTD) on Properties and Morphology: R Adhikari, **PA Gunatillake**, SJ McCarthy and GF Meijs: J. Appl. Polym. Sci. 2002, 83, 736-746 [Impact=; Citations =5]

15. New Methods for the Assessment of in vitro and in vivo Stress Cracking in Biomedical Polyurethanes: DJ Martin, LA Poole-Warren, **PA Gunatillake**, SJ McCarthy, GF Meijs and K Schindhelm: Biomaterials, 2001, 22, 973-978 [Impact=6.262 ; Citations =12]

16. Polydimethylsiloxane/Polyether Mixed Macrodiol Based Polyurethane Elastomers: Biostability: DJ Martin, LA Poole-Warren, **PA Gunatillake**, SJ McCarthy, GF Meijs and K Schindhelm: Biomaterials, 2000, 21, 1021-1029 [Impact=6.262 ; Citations =37]

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18. Mixed macrodiol-based siloxane polyurethanes: Effect of the comacrodiol structure on properties and morphology: Adhikari R, **Gunatillake PA**, McCarthy SJ, et al. J. Appl. Polym. Sci., 2000, 78, 2071-2082 [Impact=;1.008 Citations =19]

19. Effect of Chain Extender Structure on the Properties and Morphology of Polyurethanes based on H12MDI and Mixed Macrodiols. R Adhikari, **PA Gunatillake**, SJ McCarthy and GF Meijs: J. Appl. Polym. Sci. 1999, 74, 2979 [Impact=1.008 ; Citations =13]

20. The Influence of Composition Ratio on the Morphology of Biomedical Polyurethanes: DJ Martin, GF Meijs, **PA Gunatillake**, SP Yozghatilian and GM Renwick: J. Appl. Polym. Sci. 1999, 71, 937 [Impact=1.008 ; Citations =30]

21. The effect of diisocyanate isomer composition on properties and morphology of polyurethanes based on 4,4 '-dicyclohexyl methane diisocyanate and mixed macrodiols (PDMS-PHMO) Author(s): Adhikari R, **Gunatillake PA**, Meijs GF, et al. J. Appl. Polym. Sci. 1999, 71, 573-582 [Impact=1.008 ; Citations =4]

22. Synthesis and Characterisation of a Series of Poly(alkylene carbonate) Macrodiols and the Effect of Their Structure on the Properties of Polyurethanes: **PA Gunatillake**, GF Meijs, SJ McCarthy, R Adhikari and N Sherrif: J. Appl. Polym. Sci. 1998, 68, 1621-1633 [Impact=1.008 ; Citations =14]

23. The Effect of Diisocyanate Isomer Composition on Properties and Morphology of Polyurethanes Based on 4,4'-Dicyclohexyl MethaneDiisocyanate and Mixed Macrodiols (PDMS-PHMO): R Adhikari, **PA Gunatillake**, GF Meijs and SJ McCarthy: J. Appl. Polym. Sci., 1998, 73, 573-582 [Impact=1.008 ; Citations =4]

24. Synthesis, Characterisation, and Stability of Poly[(alkylene oxide) ester] Thermoplastic Elastomers: SJ McCarthy, GF Meijs and **PA Gunatillake**: J. Appl. Polym. Sci. 1997, 65, 1319 [Impact=1.008 ; Citations =4]

25. In-Vivo degradation of Polyurethanes: Transmission -FTIR microscopic characterisation of Polyurethanes Sectioned by cryomicroscopy: SJ McCarthy, GF Meijs, N Mitchell, **PA Gunatillake**, G Heath, A Brandwood and K Schindhelm: Biomaterials 1997, 18(21), 1387 [Impact=6.262 ; Citations =35]

26. Polyurethane Elastomers with Low Modulus and Hardness Based on Novel Copolyether Macrodiols: **PA Gunatillake**, GF Meijs, SJ McCarthy and N Sherrif: J. Appl. Polym. Sci. 1997, 63, 1373 [Impact=1.008 ; Citations =3]

27. The Effect of Average Soft Segment Length on Morphology and Properties of a Series of Polyurethane Elastomers. II SAXS-DSC Annealing Study: DJ Martin, GF Meijs, **PA Gunatillake**, GM Renwick and SJ McCarthy: J. Appl. Polym. Sci. 1997, 64, 803 [Impact=6.262 ; Citations =62]

28. The Effect of Average Segment Length on Morphology and Properties of a Series of Polyurethane Elastomers, Part I: Characterisation of the Series: DJ Martin, GF Meijs, GM Renwick, **PA Gunatillake** and SJ McCarthy: J. Appl. Polym. Sci. 1996, 62, 1377 [Impact=1.008 ; Citations =39]

29. The Effect of Soft Segment CH2O Ratio on Morphology and Properties of a Series of Polyurethane Elastomers: DJ Martin, GF Meijs, GM Renwick, **PA Gunatillake** and SJ McCarthy: J. Appl. Polym. Sci. 1996, 60, 557 [Impact=1.008 ; Citations =53]

30. Surface Modification of Kaolin. 2. Enhanced Steric Stabilisation of Polymer-Modified Kaolin: M Molphy, DE Mainwaring, **PA Gunatillake**, E Rizzardo and RL Laslett: Polym. Int., 1995, 37, 53 [Impact=; Citations =0]

31. In-vivo Evaluation of Polyurethanes Based on Novel Macrodiols and MDI: A Brandwood, GF Meijs, **PA Gunatillake**, KR Noble, K Schindhelm and E. Rizzardo. J Biomater Sci Polymer Edn 1994, 6, 41 [Impact=; Citations =11]

32. Surface Modification of Kaolin: M Molphy, RL Laslett, **PA Gunatillake**, E Rizzardo and DE Mainwaring: Polym. Int., 1994 , 34 ,425 [Impact=; Citations =7]

33. Zwitterion Polymerization of 1-[(4- carboxyphenyl) methyl] quinuclidinium Hydroxide Inner Salt: C Lu, **PA Gunatillake** and G. Odian: Macromolecules 1992, 25, 4464

34. Novel Polyetherurethaneurea Elastomers Based on a,a,a, a -Tetramethyl-m-xylenediisocyanate: Synthesis, Characterization, Processability and Hydrolytic Stability: **PA Gunatillake**, GF Meijs, E Rizzardo, SJ McCarthy, RC Chatelier, A Brandwood and K Schindhelm: J. Appl. Polym. Sci. 1993, 47, 199-210 [Impact= 1.008: Citations =3]

35. Influence of Stress on Novel Biomedical Polyurethanes: A Brandwood, KR Noble, K Schindhelm, GF Meijs, **PA Gunatillake**, RC Chatelier, SJ McCarthy and E Rizzardo: Adv. Biomater., 1992, 10 (Biomaterial -Tissue Interfaces), 413-419 [Impact=; Citations =2]

36. A Comparison of In Vivo Degradation of Novel Polyurethanes with Performance in In Vitro Accelerated Tests: A. Brandwood, KR Noble, K Schindhelm, GF Meijs, **PA Gunatillake**, RC Chatelier, SJ McCarthy and E Rizzardo: Dauner M. (Ed) Degradation Phenomena in Polymeric Biomaterials, Springer-Verlag, Berlin 1992, 59-66

37. Improved Polymers for Medical Implants – Polyurethanes: GF Meijs, **PA Gunatillake**, E Rizzardo, SJ McCarthy, RC Chatelier, A Brandwood and K Schindhelm: Progress in Pacific Polymer Science: Proc. 2nd Pacific Polym. Fed. (Y. Imanishi, Ed.) 1992, p 314

38. Polyurethane Elastomers, Based on Novel Macrodiols and MDI: Synthesis, Mechanical Properties and Resistance to Hydrolysis and Oxidation: **PA Gunatillake**, GF Meijs, E Rizzardo, RC Chatelier, SJ McCarthy, A Brandwood and K Schindhelm: J. Appl. Polym. Sci., 1992, 46, 319 [Impact=1.008; Citations =30]

39. Synthesis and Characterisation of Hydroxy -Terminated Poly (alkylene oxides) by condensation Polymerization: **PA Gunatillake**, GF Meijs, RC Chatelier, DM McIntosh, E Rizzardo: Polymer International, 1992, 27, 275 [Impact= Citations =20]

40. Zwitterion Polymerization of Tetrahydro-1-[4-hydroxy-3-(2-hydroxyethoxy)phenyl] thiophenium Hydroxide: G Odian, MP O'Callaghan, C-K Chien, **PA Gunatillake** and M Periyasamy: Macromolecules, 1990,23,918-925 [Impact=; Citations =4]

41. Zwitterion Polymerization of 1-[(4-Carboxyphenyl)methyl] tetrahythiophenium Hydroxide Inner Salt: **PA Gunatillake**, G Odian DL Schmidt: Macromolecules 1989, 22, 1522 [Impact=; Citations =2]

42. Thermal Polymerization of 2-(Carboxyalkyl)-2-oxazoline: **PA Gunatillake**, G Odian and D Tomalia: Macromolecules 1988, 21, 1556 [Impact=; Citations =32]

43. Cashew Nut Shell Liquid: Extraction and Properties: RA Rajapakse, **PA Gunatillake** and KB Wijekoon: J. Natn. Sci. Coun. Sri Lanka 1977, 52, 117

44. Thermal Polymerization of 2-(Mercaptoalkyl)-2-oxazoline: **PA Gunatillake**, G Odian and D Tomalia: Macromolecules 1987, 20, 2356 [Impact=; Citations =18]

45. Zwitterion Polymerization of Tetrahydro-1-(4-hydroxyl-1-naphthyl) thiophenium hydroxide Inner Salt: **PA Gunatillake**, G Odian and DL Schmidt: Macromolecules 1986, 19, 1979 [Impact=; Citations =8]

46. Zwitterion Polymerization of 2-Methyl-2-oxazoline and Methacrylic acid G Odian, **PA Gunatillake** and D Tomalia: Macromolecules 1985, 18, 605 [Impact=; Citations =32]

47. Zwitterion Polymerization of 2-Methyl-2-oxazoline and Acrylic Acid: G Odian and **PA Gunatillake**: Macromolecules 1984, 17, 1297 [Impact=; Citations =4]

48. Zwitterion Polymerization of 2-Methyl-2-oxazoline and Acrylic Acid: Characterization of Ether-soluble Products: **PA Gunatillake** and G Odian: Macromolecules 1984, 17, 2236 [Impact=; Citations =0]

BOOK CHAPTERS AND OTHER ARTICLES

1. **PA Gunatillake**, R. Mayadunne, R Adhikari. "Recent Developments in Synthetic Biodegradable Polymers. Biotechnology Annual Reviews (Elsevier) Volume 2006, 12, 301-347

2. **PA Gunatillake**, GF Meijs, SJ McCarthy. "Developments in Design and Synthesis of Biostable Polyurethanes", in Biomedical Applications of Polyurethanes Eds Vermette, Griesser, Laroche, Guidoin, Landes Bioscience, Texas. 2001, 160-170(For an electronic copy see: http://www.eurekah.com/reports/tissueengineering/index.html)

3. **PA Gunatillake**, GF Meijs, SJ McCarthy. "Commercial Production of Polyurethanes, in Biomedical Applications of Polyurethanes", Eds Vermette, Griesser, Laroche, Guidoin, Landes Bioscience, Texas. 2001, pp22-48 (For an electronic copy see: http://www.eurekah.com/reports/tissueengineering/index.html)

4. **PA Gunatillake**, GF Meijs. "Polyurethanes in Biomedical Engineering", Encyclopedia of Materials: Science and Technology, Elsevier Science 2001, pp 7746-7753

INVITED LECTURES, INDUSTRY PRESENTATIONS AND WORK SHOPS

NOTE: Since joining PolyNovo numerous presentations on NovoSorb technology were made to research/management teams in major medical device manufacturers including, Medtronic Vascular, Sofomor Danek, Johnson & Johnson, Osteotech, Syntheses, Biomet, and Smith & Nephew.

1. Technology Commercialization-PolyNovo. AusMedTech Seminar Nov 13, 2008. Sydney
2. Injectable Biodegradable Polyurethanes for Tissue Engineering. 7th Biomaterials World Congress, May 2004, Sydney Australia
3. Injectable Polymers in Tissue Engineering, University of Liverpool, Department of Clinical Engineering, Prof David Williams Research Group, Oct 14, 2003
4. Biodegradable Polymers, University of Wisconsin, School of Pharmacy, Madison Wisconsin, USA, Oct 21, 2003
5. Polyurethane in Biomedical Engineering, Far Eastern Textiles R&D Centre, Taiwan, Nov 2, 2003
6. Polymers for Biomedical Implants, Joint Public Seminar Organised by Society of Plastics Engineers and AusBioTech, 2003
7. Development of Low Modulus Biostable Polyurethanes: Plenary Lecture, Symposium on Polymers in Dentistry Medicine and Surgery: Brisbane, Feb 6-8, 2002
8. Polyurethanes- Versatile Biomaterials" AorTech Corporate Forum, 28th Annual Meeting of the Society For Biomaterials, Tampa, Florida, April 24-27, 2002

9. Processing and Evaluation of Siloxane-Polyurethanes for Biomedical Applications" AorTech Corporate Forum, 27th Annual Meeting of the Society For Biomaterials, Saint Paul, MN April 24-29, 2001

10. Development of Polyurethanes for Medical Implants: Plastic and Rubber Institute of Sri Lanka, Jan 2001, ITI Sri Lanka

11. Polyurethanes in Biomedical Engineering: Sri Jayawardenapura University , Sri Lanka, Jan 2001

12. Polyurethanes in Biomedical Engineering: RACI Polymer Summer School, Lake Hume Resort, Feb 2001

13. Evaluation of polyurethanes for Medical Implant Applications: Elastomedic Corporate Forum, Sixth Word Biomaterials Congress, Kamuela, Hawaii, May 15-20th, (2000)

CONFERENCE PAPERS

Dr Gunatillake has presented or co-authored over 75 conference presentations to both local and international conferences during his tenure with CSIRO and only the some those presented after 2000 are listed here.

1. In-Vitro Degradation of NovoSorb Polyurethanes designed for Orthopaedic Applications Adhikari R, Tatai L, Mayadunne RTA, Moore T, Houshyar S, Hanu L, Wickramarathna M, Menzies D, Johnson P, **Gunatillake PA**, Proceeding 28th Australasian Polymer Symposium, 5-9 Feb, 2006, pE3/3

2. Biodegradable NovoSorb Polymers: Structure/Property Relationship & In-vitro/In-Vivo Degradation. Mayadunne RTA, Adhikari R, Tatai L, Moore T, Houshyar S, Hanu L, Wickramarathna M, Menzies D, Johnson P, **Gunatillake PA**, Proceeding 28th Australasian Polymer Symposium, 5-9 Feb, 2006, pE3/3

3. Adhikari R, **Gunatillake PA**, Mayadunne RTA, et al, Proceedings 30th Annual meeting, Society For Biomaterials, Memphis, TN. USA, 2005, p442.

4. **Gunatillake PA** and Adhikari R et al 7th World Biomaterial Congress, Sydney May 2004, p703.

5. Effect of Sulfonium Zwitterions on Properties and Degradation of Biodegradable Polyurethanes. Adhikari R, **Gunatillake PA**, Le, TPT, Danon, SJ, Seymour, K, Bean P, Werkmeister, JA, Ramshaw, JAM, White, JF, Glattauer, V and Tebb TA. 7th World Biomaterial Congress, Sydney May 2004, p621.

6. Long Term *in vivo* Biostability of Poly(dimethylsiloxane)/poly(hexamethylene oxide) Mixed Macrodiol-based Polyurethane Elastomers. Simmons, A1, Hyvarinen, J1, Odell, RA1, **Gunatillake, PA**, Martin, DJ, Noble, KR1 and Poole-Warren, LA. 7th World Biomaterial Congress, Sydney May 2004, p1862.

7. Preliminary In Vivo Evaluation Of A Polymeric Adhesive For Meniscal Defect Repair. Field J.R., **Gunathilak PA.**, Adhikari R , Werkmeister J , Ramshaw J 7th World Biomaterial Congress, Sydney May 2004, p333.

8. Effect of Cross Linking on Creep Resistance of Biostable Polyurethanes **Gunatillake, PA**, Adhikari, R , Le, **TPT**, Padsalgikar, AD, Weksler, J, Griffiths, IM. 7th World Biomaterial Congress, Sydney May 2004, p1591.

9. Non Elastomeric Siloxane Polyurethanes: Adhikari R., **Gunatillake PA.**, McCarthy SJ., Meijs GF., , Australian Society for Society for Biomaterials, Brisbane, April 2003

10. Siloxane Based Polyurethanes and Polyurethaneureas for Medical application: Adhikari R., Bown, M., **Gunatillake PA** and McCarthy SJ., Meijs GF.,: The CSIRO-Aortech Biomaterials Technology transfer story, International Conference on Advances of Biomaterials for Reconstructive Medicine, OC32, Italy, June 9-14, 2002

11. The Effect of PDMS Molecular weight on morphology and properties: Adhikari R., **Gunatillake PA.**, Bown, M., McCarthy SJ., Meijs GF., 28th Annual Meeting, Society for Biomaterials, Tampa, USA, April 2002

12. The Effect of PDMS Molecular weight on morphology and properties: Adhikari R., **Gunatillake PA.**, Bown, M., McCarthy SJ., Meijs GF., , Australian Society for Biomaterials, Canberra, March, 2002

13. The Effect of Chain Extender Structure on Properties, Morphology and Biostability of Siloxane Polyurethanes: **Gunatillake PA.**, Adhikari R., Bown, M., McCarthy SJ., Meijs GF., , 28th Annual Meeting, Society for Biomaterials, Tampa, Florida, USA, April 2002

14. Siloxane-Based Polyurethaneureas: Synthesis and Properties: Adhikari R., **Gunatillake PA.**, Bowen, M., McCarthy SJ., Meijs GF., , 27th Annual Meeting, Society for Biomaterials, Minneapolis, USA, p 170, April 2001

15. The Effect of Chain Extender Structure on Properties, Morphology and Biostability of Siloxane Polyurethanes: **Gunatillake PA.**, Adhikari R., Bown, M., McCarthy SJ., Meijs GF., , 27th Annual Meeting, Society for Biomaterials, Minneapolis, USA, p 128,April 2001

16. Siloxane-Polyurethaneureas: Synthesis and Properties:
R Adhikari, **PA Gunatillake**, M Bown, GF Meijs, L A Simmons, J Hyvarinen, SJ McCarthy, K Noble. 27th Annual Meeting of the Society for Biomaterials, April 24-29, Saint Paul, USA, p 170, 2001

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